510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 576 - 3544

Contact Person: Kay A. Taylor

Date Prepared: September 9, 2000

Device Name

Proprietary name: Elecsys® DHEA-S

Common name: DHEA-S

Classification name: Radioimmunoassay, Dehydroepiandrosterone (Free and Sulfate)

Device Description

The Elecsys® DHEA-S Assay is based on a competitive immunoassay with streptavidin microparticles and electrochemiluminescence detection.

Results are determined using a calibration curve that is generated specifically on each instrument by a 2-point calibration and a master curve provided with the reagent bar code card.

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510(k) Summary, Continued

Intended use

For the in vitro quantitative determination of dehydroepiandrosterone sulfate in human serum and plasma.

Indications for Use

The determination of elevated DHEA-S values is an important aid in the diagnosis of hirsutism and virilism. Further indications for this parameter are all forms of androgenisation, hyperprolactinemia, polycystic ovarian syndrome and the eclusion of an androgen producing tumorof the adrenal cortex.

Substantial Equivalence

The Elecsys® DHEA-S is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the DPC Immulite DHEA-SO_4 (K935806).

Substantial equivalence - similarities

The following table compares the Elecsys® DHEA-S Assay with the predicate device.

Feature	Elecsys® DHEA-S	Immulite DHEA-SO_4
Intended Use	For the in vitro quantitative determination of dehydroepiandrosterone sulfate in human serum and plasma.	For the quantitative determination of dehydroepiandrosterone sulfate in serum. Intended strictly for in vitro diagnostic use.
Indication for Use	The determination of elevated DHEA-S values is an important aid in the diagnosis of hirsutism and virilism. Further indications for this parameter are all forms of androgenisation, hyperprolactinemia, polycystic ovarian syndrome and the eclusion of an androgen producing tumorof the adrenal cortex.	Measurement of dehydroepiandrosterone sulfate is important to investigations of abnormal hair growth (hirsutism) and balding (alopecia) in women. It is also of value in the assessment of adrenarche and delayed puberty.

Substantial equivalence - similarities

The following table compares the Elecsys® DHEA-S Assay with the predicate device.

Feature	Elecsys® DHEA-S	Immulite DHEA-SO_4
Assay Protocol	Competitive assay	Competitive assay
Detection Protocol	Electro-chemiluminescence	Chemiluminescence

Substantial equivalence - differences

The following table compares the Elecsys® DHEA-S assay with the predicate device.

Feature	Elecsys® DHEA-S	Immulite DHEA-SO_4
Instrument	Elecsys Immunoassay Analyzers	Immulite Systems
Sample Type	Serum & Plasma	Serum
Traceability / Standardization	Gravimetrically produced Master calibrators with defined DHEA-S concentrations.	Not in package insert
Measuring Range	0.10 - 1000 µg/dl	30 - 1000 µg/dl

Substantial equivalence – performance characteristics, cont.

The performance characteristics of the Elecsys® DHEA-S Assay and the predicate device are compared in the table below.

Feature	Elecsys® DHEA-S	Immulite DHEA-SO_4
Intra-assay precision (% CV)	Human sera: 2.8% at 117 µg/dl 2.4% at 395 µg/dl 1.7% at 984 µg/dl	7.6% at 45 µg/dl 9.2% at 89 µg/dl 9.5% at 189 µg/dl 8.1% at 421 µg/dl 6.8% at 783 µg/dl
	Controls: 2.2% at 153 µg/dl 2.8% at 123 µg/dl	

Substantial equivalence – performance characteristics, cont.

The performance characteristics of the Elecsys® DHEA-S Assay and the predicate device are compared in the table below.

Feature	Elecsys® DHEA-S	Immulite DHEA-SO_4
Total Precision (% CV)	Human sera: 3.6% at 117 µg/dl 4.7% at 395 µg/dl 2.4% at 984 µg/dl Controls: 2.6% at 153 µg/dl 3.1% at 123 µg/dl	15% at 162 µg/dl 13% at 552 µg/dl 8.1% at 899 µg/dl
Limitations	• No interference from bilirubin up to 13 mg/dl. • No interference from lipemia (Intralipid) up to 2000 mg/dl. • No interference from biotin up to 36 ng/ml. • No interference from rheumatoid factors up to 600 U/ml. • In rare cases, interference due to extremely high titers of antibodies to streptavidin can occur.	• No clinically significant interference from bilirubin • No clinically significant interference from hemolysis • Use of an ultracentrifuge is recommended to clear lipemic samples.
Analytical sensitivity (LDL)	0.10 µg/dl	0.07 µg/dl
Method comparison	Elecsys DHEA-S (Y) / Immulite DHEA-SO4 (X): Bablok- Passing Y= 1.06x + - 4.78, r= 0.952 Linear Reg: Y= 0.94x + 14.0, r = 0.952	Immulite DHEA-SO4 (Y)/DPC Coat-A-Count DHEA-SO4 RIA (X) Y= 1.01x – 7.0 r = 0.985

Substantial equivalence – performance characteristics, cont.

The performance characteristics of the Elecsys® DHEA-S Assay and the predicate device are compared in the table below.

Feature	Elecsys® DHEA-S	Immulite DHEA-SO_4
Calibration frequency	Once per reagent lot using fresh reagent. Elecsys 2010 • After 1 month (same reagent lot) • After seven days (same kit on analyzer) • As required by QC protocols Elecsys 1010 • With every reagent kit • After seven days (ambient temperature 20-25°C) • After three days (ambient temperature 25-32°C) • As required by QC protocols	• Each new kit lot. • After seven days with same kit in use.
Expected values	20 - 150 µg/dl Newborn 5 – 30 µg/dl < 6 years 20 – 100 µg/dl Adrenarche 70 - 300 µg/dl Females (Premenopausal) 20 – 100 µg/dl Females (Postmenopausal) 100 – 300 Men	35 – 430 µg/dl females 80 – 560 µg/dl males

Substantial equivalence – performance characteristics, cont.

The performance characteristics of the Elecsys® DHEA-S Assay and the predicate device are compared in the table below.

Feature	Elecsys® DHEA-S	Immulite DHEA-SO_4
Specificity	Percent cross reactivity at concentration tested: Cortisol= 0.004% @ 10,000 µg/dl Androstendione= 0.399% @ 1000 µg/dl DHEA= 0.178% @ 1000 µg/dl Androsterone= 0.033% @ 2000 µg/dl Testosterone= 0.033% @ 2000 µg/dl Androsterone-glucuronide= 0.014% @ 5000 µg/dl Androsterone-sulfate= 0.137% @ 5000 µg/dl 5-α-dihydrotestosterone= 0.028% @ 5000 µg/dl DHEA-glucuronide= 0.020% @ 5000 µg/dl Estradiol-3-sulfate-17-glucuronide= 0.009 @ 5000 µg/dl 19-hydroxyandrostendione= 0.018% @ 5000 µg/dl Aldosterone= 0.008% @ 5000 µg/dl Estrone= 0.012% @ 5000 µg/dl Estradiol= 0.005% @ 5000 µg/dl Estriol= 0.006% @ 5000 µg/dl Estrone-3-sulfate= 0.136% @ 5000 µg/dl Progesterone= 0.034% @ 5000 µg/dl	Percent cross reactivity at concentration tested: DHEA= 0.049% @ 4000 µg/dl DHEA-Glucuronide= 0.054% @ 5000 µg/dl Aldosterone= 0.003% @ 5000 µg/dl Androstenedione= 0.147% @ 1000 µg/dl Androsterone0.028% @ 2000 µg/dl Androsterone-Glucuronide= 0.015% @ 5000 µg/dl Androsterone-SO4= 0.231% @ 5000 µg/dl Cortisol= 0.001% @ 10,000 µg/dl 5-α-dihydrotestosterone= 0.028% @ 5000 µg/dl Estradiol= Nondetectable β-estradiol-3-SO4-17-glucuronide= 0.005% @ 5000 µg/dl Estriol= Nondetectable Estrone= 0.005% @ 5000 µg/dl Estrone-3-SO4= 0.495% @ 5000 µg/dl 19-Hydroxyandrostendione= 0.011% @ 5000 µg/dl Progesterone= 0.012% @ 5000 µg/dl Testosterone= 0.042% @ 2000µg/dl

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 7 2001

Ms. Kay A. Taylor
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
PO Box 50457
Indianapolis, Indiana 46250-0457

Re: K003174
Trade Name: Elecsys® DHEA-S
Regulatory Class: I
Product Code: JKC
Dated: January 2, 2001
Received: January 3, 2001

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarke notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): N/A K003174

Device Name: Elecsys® DHEA-S

Indications For Use:

For the in vitro quantitative determination of dehydroepiandrosterone sulfate in human serum and plasma. The determination of elevated DHEA-S values is an important aid in the diagnosis of hirsutism and virilism. Further indications for this parameter are all forms of androgenisation, hyperprolactinemia, polycystic ovarian syndrome and the eclusion of an androgen producing tumor of the adrenal cortex.

(Division Sign-Off)
Division of Clinical Laborato... ...vices
510(k) Number K003174

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)